REMARKS

I. STATUS OF THE CLAIMS:

Claims 1-28 are pending. Claims 1, 10, 18, 19, 22-24, 26 and 27 have been amended. Applicant respectfully submits that no new matter has been added by virtue of this Amendment.

II. REJECTION UNDER 35 U.S.C. § 112

In the Office Action, the Examiner rejected Claim 19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that "it is not clear to the examiner what weight ratio is being used in claim 19, is the ratio NSAID/(xanthan gum + locust bean gum) or is the ratio (xanthan gum + locust bean gum)/NSAID." The Examiner indicated that the latter ratio (xanthan gum + locust bean gum)/NSAID) was used for examination purposes.

Claim 19 of the present invention recites, *inter alia*:

> An oral sustained release dosage form, ...; wherein the weight ratio of said ibuprofen to the combined weight of said xanthan gum and said locust bean gum is from about 1:0.06 to about 1:0.4.

Accordingly, it is clear from the language of claim 19 that the weight ratio of "about 1:0.06 to about 1:0.4 is the weight ratio of ibuprofen/(xanthan gum and locust bean gum). Accordingly, claim 19 is not indefinite. Therefore, Applicant respectfully requests that the Examiner's rejection of claim 19 under 35 U.S.C. § 112 be removed.

III. REJECTION UNDER 35 U.S.C. § 103(a)

A. Rejection in view of U.S. Patent No. 5,330,761 to Baichwal.

In the Office Action, the Examiner rejected Claims 1-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,330,761 to Baichwal (hereinafter "the '761 patent").

The amended independent claims of the present invention recite, *inter alia*, dosage forms, an excipient for use in a dosage form and methods of preparing dosage forms that provide effective blood plasma levels of an NSAID (e.g., ibuprofen).

In contrast, the '761 patent is directed to controlled release bioadhesive dosage forms which are administered to an environment where they contact mucous membranes and are exposed to bodily fluid, e.g., the oral cavity, periodontal pockets, surgical wounds and vaginally (See: '761 patent at col. 7, lines 8-22). The dosage forms of the '761 patent release "a[n] active ingredient which is substantially not absorbed into the body, but which instead provides a localized effect." (See: col. 2, lines 33-37) As admitted by the Examiner in the Office Action, the '761 patent "does not specifically mention ibuprofen as an active ingredient...." Furthermore, the '761 patent does not teach or suggest that the dosage forms described therein provide effective blood plasma levels of an active agent as claimed in the claims of the present invention. The '761 patent also does not teach or suggest the dissolution rate and t_{50} value as recited in independent claims 1, 10 and 18 of the present invention. Accordingly amended independent claims 1, 10, 18, 19, 22-24, 26, and 27 are not obvious over the '761 patent. As claims 2-9, 11-17, 20, 21, 25 and 28 depend from one of the amended independent claims, these dependent claims are also not obvious over the '761 patent. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

B. Rejection in view of U.S. Patent No. 5,330,761 to Baichwal in view of U.S. Patent No. 5,096,714 to Kuhrts.

In the Office Action, the Examiner rejected Claims 1-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,330,761 to Baichwal in view of U.S. Patent No. 5,096,714 to Kuhrts (hereinafter "the '714 patent). As mentioned above, The Examiner admits that the '761 patent does not specifically mention ibuprofen as an active ingredient and, therefore, relies on the '714 patent for its teaching of ibuprofen.

Applicant respectfully submits that the teachings of the '714 patent are not properly combinable with the teachings of the '761 patent. The controlled release bioadhesive dosage forms of the '761 patent release an active ingredient which is substantially not absorbed into the body, but which instead provides a localized effect. In contrast, the dosage formulations described in the '714 patent contain an active ingredient(s) that "acts systemically and which can be administered orally to transmit the active therapeutic agent into the gastrointestinal tract and into the bloodstream in therapeutically-effective levels...." (See: col. 14, line 56 to col. 15, line 7). One skilled in the art would have no motivation to combine the teachings of a patent directed to dosage forms for the systemic absorption of an active agent (e.g., the '714 patent which mentions ibuprofen) to cure the deficiencies of a patent that is directed to dosage forms wherein the active agent is substantially unabsorbed and provides a localized effect (e.g., the '761 patent).

Even if motivation were provided for one skilled in the art to combine the teachings of the '714 patent with the '761 patent, the result would not likely be the dosage forms claimed in the present invention, but instead would be controlled release bioadhesive ibuprofen dosage forms in which the active ingredient of the dosage form is substantially not absorbed into the body, but which instead provides a localized effect (e.g., the oral cavity, periodontal pockets, surgical wounds and vaginally). Accordingly amended independent claims 1, 10, 18, 19, 22-24, 26, and 27 are not obvious over the '761 patent in view of the '714 patent. As claims 2-9, 11-17, 20, 21, 25 and 28 depend from one of the amended independent claims, these dependent claims are

also not obvious over the '761 patent in view of the '714 patent. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

IV. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

In the Office Action, the Examiner rejected Claims 1-28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,093,420.

Upon receipt of a Notice of Allowance indicating that the present claims are otherwise allowed, Applicant will consider submission of a timely filed terminal disclaimer to overcome the Examiner's nonstatutory obviousness–type double patenting rejection will be considered.

V. CONCLUSION

This Response is being submitted together with a petition for a one-month extension of time under 37 C.F.R. § 1.136(a) from July 19, 2006 to August 19, 2006. A check in the amount of $120.00 is enclosed herewith to cover the fee due under 37 C.F.R. § 1.17(a)(1). It is believed that no other fees are due. If, however, it is determined that any additional fees are due or that any fee has been overpaid, the Commissioner for Patents is hereby authorized to charge said fee or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,

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